Investigations

- Suspicious Order Investigations
  - Order flagged by OMP
  - Unusual size, deviates substantially from a normal pattern, unusual frequency, item type.
  - Purchase history.
  - Dollar volume/product mix.
  - Ratio of CS to Non-CS purchases.
  - Contact with customer.
  - Is there a rationale for the order?
  - Site visit.
  - Responsibility not to ship a suspicious order.

Review of Monthly Data

- Top purchasers of high risk controls and selected non-controls.
- CS ratio report.
- Help identify potential problems.
- Analyzed in 6-month blocks.
- Trending.
- Can bring to light a problem the customer does not know exists, i.e. internal diversion.

Tramadol & Carisoprodol (Soma)

- Federal – Non-Controlled substances.
- State – CS in AL, AZ, HI, IN, KY, NV, NM, OH, OR, WV.
- Listed as "drugs of concern" by the DEA.
- High volume purchases may be indicative of Internet sales.
- Brick-n-mortar pharmacies are solicited to fill and mail prescriptions received through internet sites for a set fee.

Education and Training

- NADDI – National Association of Drug Diversion Investigators.
- Cluster meetings.
- On site training.
- Model policies and procedures.

Order Monitoring Program and Diversion Control



AmerisourceBergen® is committed, along with our supply chain partners, to preventing the diversion of controlled substances. We have taken a leadership role in developing and implementing programs that help identify instances of diversion – and it is only with your help that we ensure the safety of the pharmaceutical supply chain.

Current Regulations

One of the DEA's highest priorities nationwide is to eliminate the diversion and abuse of controlled substances. All individuals and firms who handle controlled substances must be registered with the DEA. As a DEA registered pharmacy, you are required to "provide **effective controls and procedures** to guard against theft and diversion of controlled substances." Title 21, Code of Federal **Regulations, parts 1300 to 1316.**

Furthermore, the DEA is requiring wholesalers, including AmerisourceBergen, to take a more active role in monitoring the ordering of controlled substances. In response, we have taken the lead in developing an enhanced Order Monitoring Program.

About our Order Monitoring Program

- The Order Monitoring Program is the cornerstone of our diversion control effort. The program helps to alert customers of significant changes in order quantities and can assist in resolving variances.
- Monthly controlled substance thresholds are established for each customer and are based on three factors:
  – DEA registrant type (hospital, retail, clinic, physician, etc)
  – Customer size by sales volume
  – Item family (particular classes of drugs or chemicals)
- Threshold levels for controlled substances can be adjusted depending upon your business practices and/or treatment specialty.

How AmerisourceBergen can help you

- AmerisourceBergen has developed "Pharmacy Guidelines for DEA Compliance" which are suggested Best Practices for our customers — to help you gain confidence in your compliance with DEA regulations.
- A team of dedicated investigators, analysts and support personnel will assist our customers to help prevent diversion and remain compliant with federal regulations.
- AmerisourceBergen's Corporate Security and Regulatory Affairs staff will work closely with customers to minimize impact on compliant customers' orders.

Prescription drug diversion and abuse will continue to be a serious problem with far-reaching implications for public safety and the pharmaceutical industry. AmerisourceBergen remains an industry leader in addressing those concerns — and we will continually enhance our program — for our pharmacy partners.

If you have any questions about AmerisourceBergen's Order Monitoring Program or your pharmacy's purchasing levels, contact your Account Manager.

To learn more about "Pharmacy Guidelines for DEA Compliance," contact your Account Manager or Ed Hazewski, AmerisourceBergen Diversion Control Manager at 610-727-3680 or ehazewski@amerisourcebergen.com

AmerisourceBergen

Partnering With Our Customers

- CSRA will attend cluster meetings or other customer events to present topics of concern / interest
- CSRA, in cooperation with the ABC management staff, is developing a video library for use by our customer base
- Robbery / Burglary Prevention
- Shrinkage / Loss Prevention
- Diversion Control

Rx PATROL

WWW.rxpatrol.org

An information clearinghouse about pharmacy robberies, burglaries and theft of controlled substances

Collects, analyzes and shares information to:

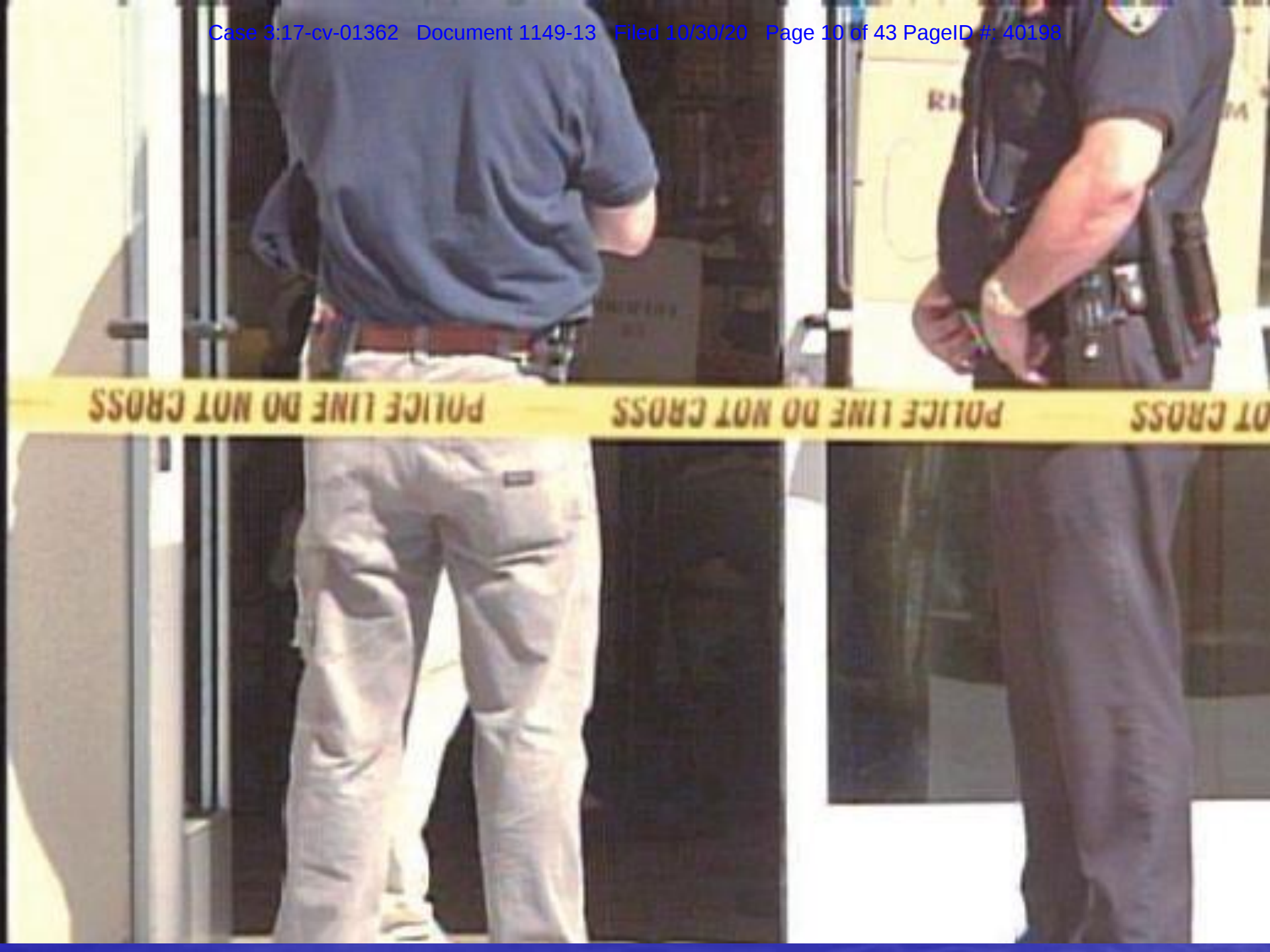
- Help protect pharmacists
- Guard against potential robberies and burglaries
- Assist law enforcement efforts to apprehend and successfully prosecute those engaged in pharmacy theft of controlled substances

Uses state-of-the-art computer program to collate, analyze and disseminate information to the law enforcement community.

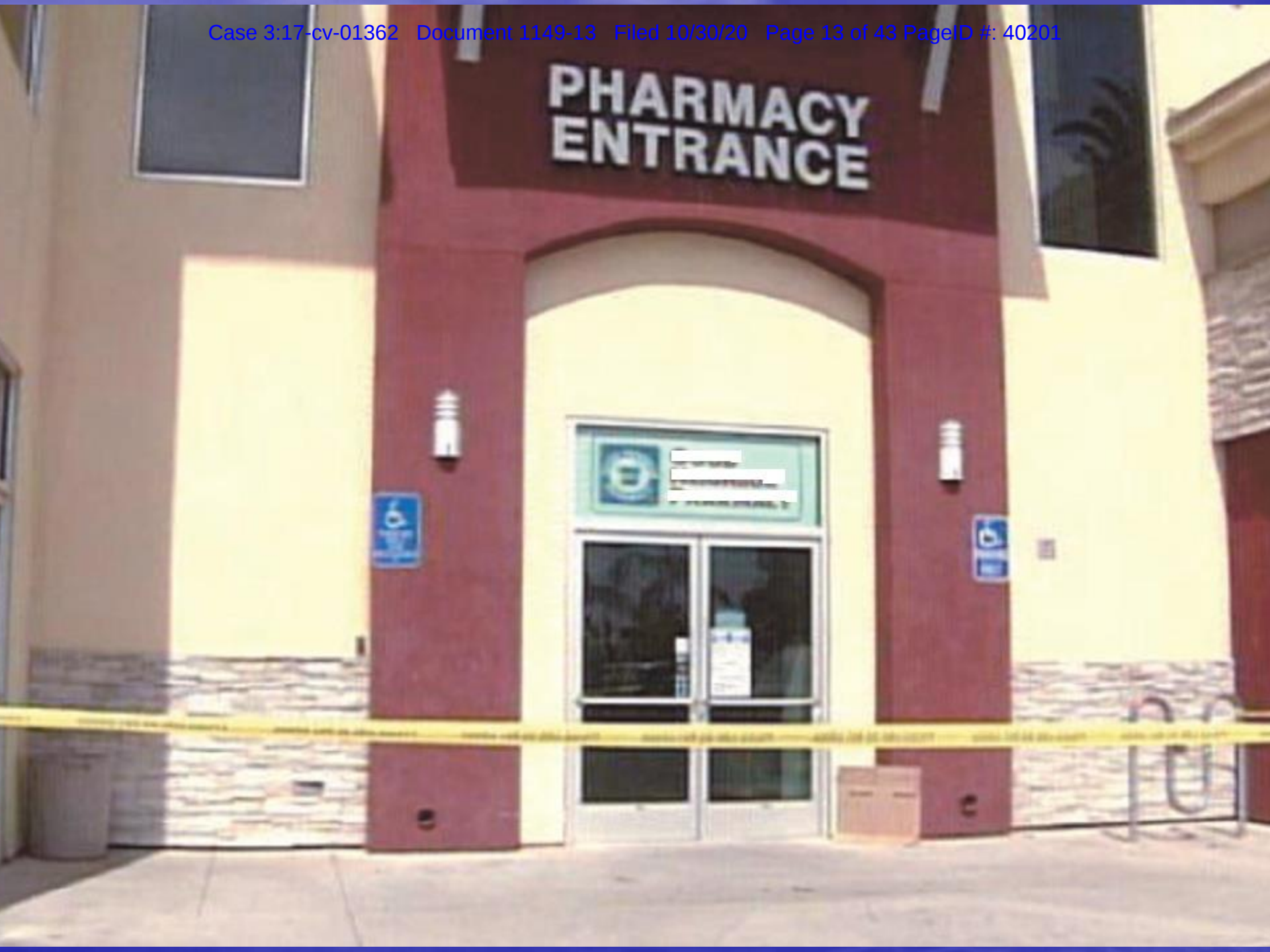
Analyzes patterns to create profiles of vulnerable pharmacies and of effective security systems for deterring burglars and robbers.

Training Videos – Pharmacy Safety, Scams, Diversion

WHAT WE DON'T WANT


POLICE LINE DO NOT CROSS
POLICE LINE DO NOT CROSS


PHARMACY
LOW PRICE
PHARMACY


PHARMACY
ENTRANCE

WHAT CAN YOU DO?

Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

1301.71(a) – "**All applicants and registrants** shall provide **effective controls** and **procedures** to guard against theft and diversion of controlled substances."

ABC Model Policies & Procedures For Retail Pharmacies

- Based on industry best practices and the Code of Federal Regulations.
- Addresses issues concerning the ordering, receiving, security, and handling of controlled substances.
- Intended to be a model for ABC pharmacy customers to follow to develop their own P & Ps.
- A valuable tool in assisting the pharmacy to keep compliant with Federal and State law and regulations.

Policies & Procedures

- Introduction – Logic & "Best Practices"
- Areas to Include in Policies & Procedures
  - DEA Registration
  - Recordkeeping
  - Ordering and Receipt of Controlled Substances
  - Security and Storage
  - Inventory

Policies & Procedures

- Policy & Procedure Areas, cont.:
  - "Disposal" of Controlled Substances
  - Diversion
  - Methamphetamine Control Act
  - Prescriptions
  - Controlled Substance Dispensing
  - Pain Clinic Patients

Controlled Substance Prescriptions "Know Your Customer"

- Patient Name and Address
- Date Written
- Drug Name, Strength, Directions, & Quantity
- Prescribing Physician's Name, Address & DEA #
- Need All the Above **AND** Patient has a Legitimate Medical Reason for the Prescription to be Valid

Dispensing

- Visually Inspect Prescriptions for Potential Forgery and/or Alteration
- Review Patient Profile for Appropriateness of Therapy
- Review State Prescription Monitoring Data (if available) or Make Other Attempts to Determine Multiple Prescribers/Pharmacies
- Phone Verify All New Patients and Prescriptions From Unknown Physicians

Dispensing

- You Want How Many?
  - Validate the Appropriateness of what the Physician Writes
- Limit Who Can Pick Up Prescriptions to Only Those Authorized by the Patient
- Require Identification for Prescription Pick Up

Pain Clinic Patient Management

- Pain Clinic's Prescribers Should be Open and Willing Participants to Answer Questions
- Pain Clinic Implemented "Pain Contracts" with Patients to Spell Out the Patient's Rights and Responsibilities Regarding Pain Therapy
- Pharmacy Maintains Copies of Those Contracts if possible
- Medication "Counts"
- Prescriptions Tamper Resistant

Pain Clinic Patient Management

- Set a Minimum Fill Time (recommend at least 30 min)
- Establish a Procedure for "Lost" or Stolen Prescriptions & Medications that Includes Notification of the Police and Prescriber
- Establish Routine "Training Programs" for Pharmacy Staff that Focuses on Identification of Fraudulent Prescriptions & Patients
- Establish Routine Documentation Procedures for Conversations with the Pain Clinic Staff and for Situations that Arise for the Patient While on Service

Recent Federal and State Regulatory Activity

Ryan Haight Online Pharmacy Consumer Protection Act

- Legislation enacted on 10/15/2008
- Amends the CSA adding new provisions to prevent illegal distribution of controlled substances by Internet
- Expands the definition of valid prescription to include at least one "face-to-face" medical evaluation

Ryan Haight Online Pharmacy Consumer Protection Act

- New DEA registration requirements for all Internet pharmacies
  - Modification of existing DEA pharmacy registration
  - New DEA number identifier and business activity code
- Reporting requirements
  - Number of prescriptions, dosage unit totals

Ryan Haight Online Pharmacy Consumer Protection Act

- Disclosure requirements for Internet pharmacy's home page
  - Identify and post address and phone number of servicing pharmacies, pharmacist in charge and physicians
- Effective date of 4/13/2009
- Requires rulemaking by DEA concerning telemedicine
- **DEA has received five (5) applications as of the end of June 2009**…….????

Prescription Drug Disposal

- FDA Drug Disposal Guidelines Published 6/2008
- Office of National Drug Control Policy reiterated those Guidelines 1/2009
- Focus is medications in the public's possession that are "no longer in use"
- Doesn't differentiate prescription meds from controlled substances disposal

Prescription Drug Disposal

- Federal Guidelines:
  - Don't flush unless there is specific instruction to do so (on label or patient information)
  - Check for community drug take back programs or household hazardous waste collection events that include medications

Prescription Drug Disposal

- If drug take back or collection not available
  - Remove medications from original container
  - Mix drugs with "undesirable" substance (cat litter or coffee grounds) and seal in a plastic container or sealable bag
  - Remove any personal information from the empty original containers
  - Place sealed container with medication mixture and empty drug containers in trash

Prescription Drug Disposal

- Federal Legislative Efforts to Address Prescription Drug Disposal:
  - Clean Water Act (EPA)
  - Universal Waste Rule (EPA) – Addition of Pharmaceuticals (Pending)
  - Drug Free Water Act of 2009 (EPA) (Pending)
  - Safe Drug Disposal Act of 2009 (DEA) (Pending)
  - DEA ANPRM "Disposal of controlled substances by persons not registered with the Drug Enforcement Administration" (1/2009)

Prescription Drug Disposal

- Other Efforts
  - State Legislation (Maine, Oregon, Wash)
  - Pharmacy & Hospital collection events (single day & ongoing)
  - Municipal or county events (single day)
  - Maine mail back program
  - Reverse Distributor pilot (WI)

Controlled Substance Disposal

- ANPRM Published in Federal Register on 1/21/2009
- Entitled "Disposal of Controlled Substances by Persons Not Registered With the Drug Enforcement Administration"
- Seeks options for safe and responsible disposal of patient-owned controlled substances consistent with CSA

Methamphetamine Production Prevention Act of 2008

- Enacted on 10/14/2008
- Amends the CSA adding new provisions regarding logbook requirements
- Permits mix of manual and electronic
- Allows certain info to be captured electronically, while other info is captured in a written log.

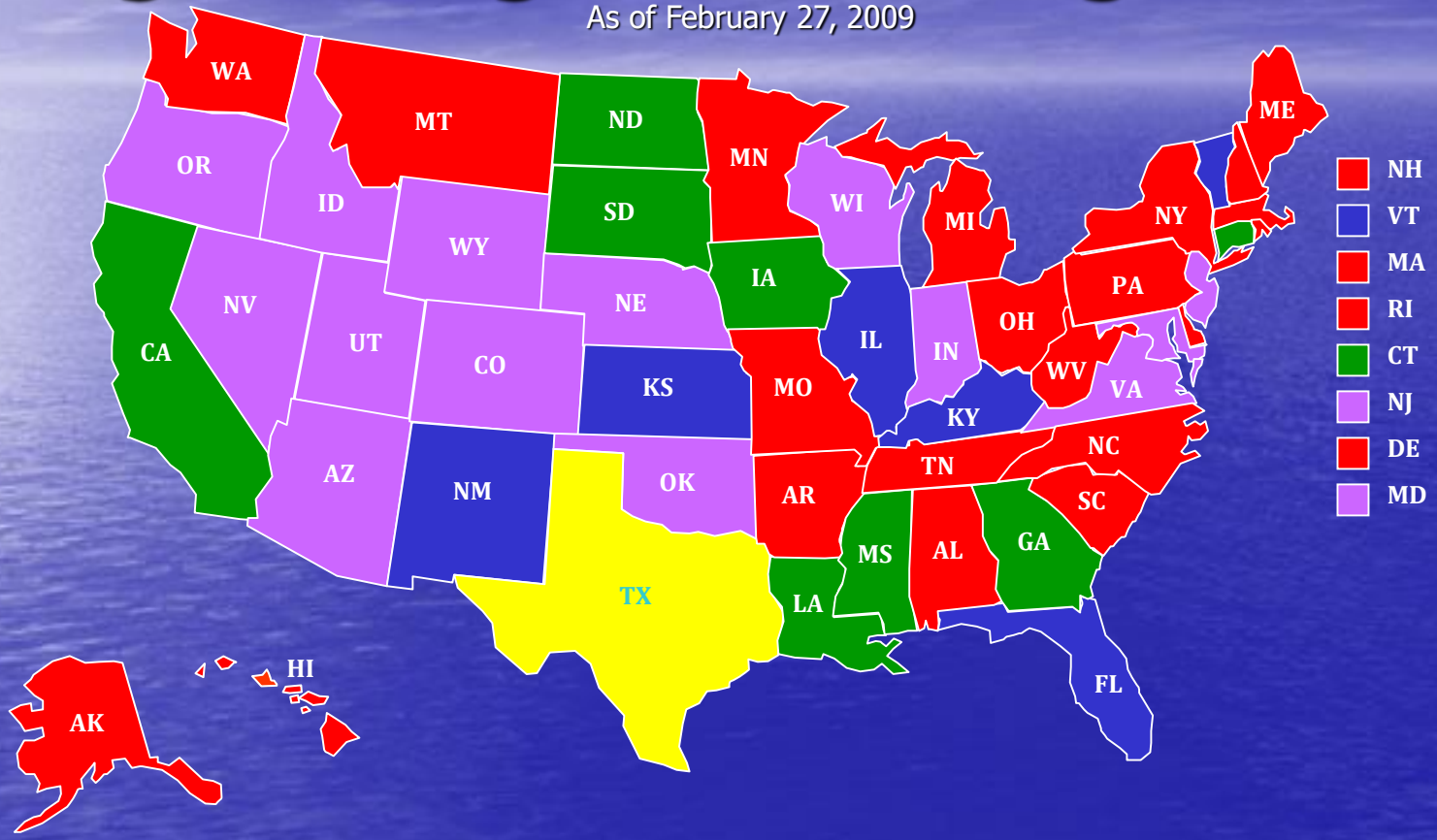
Federal PDMA Timeline

State Pedigree Update

- Between 2003-2009, 28 states enacted some form of pedigree legislation
  - "Normal" or "Primary" Distribution Model in 19 states (AZ, CO, GA, ID, IL, IN, KS, MD, MS, NE, ND, OK, OR, SD, TX, VA, WI. WY)
  - Requires pedigree (back to manufacturer) outside designated distribution channel
  - Seven others adopted PDMA or similar models
  - California – "Track and Trace" Model
  - Florida – Standard or "Direct Purchase" Pedigree

2009 HDMA Map of State Pedigree Legislation/Regulations

As of February 27, 2009



FDA's Risk Evaluation and Mitigation Strategies (REMS)

- Food & Drug Amendments Act of 2007 provides FDA with Authority to:
  - Require post-marketing studies and clinical trials
  - To demand safety related labeling changes
  - Demand the development and compliance with REMS

FDA's Risk Evaluation and Mitigation Strategies (REMS)

- FDA Established Guidelines for:
  - New Drug Applications (NDA)
    - Criteria used to determine need for REMS includes:
      - **Size of population likely for treatment**
      - **Seriousness of disease**
      - **Anticipated drug benefit**
      - **Anticipated duration of therapy**
      - **Adverse event potential**
      - **Medication molecular make up (similar to something already on market or new formulation)**

FDA's Risk Evaluation and Mitigation Strategies (REMS)

- REMS Elements:
  - Required
    - Assessment submission timetable
  - Optional
    - MedGuide
    - Communication Plan
    - Elements to Assure Safe Use (EASU)
    - Implementation System

FDA's Risk Evaluation and Mitigation Strategies (REMS)

- EASU Examples:
  - Prescribers of the drug have specialized training/experience or certification
  - Dispensers of the drug are specially certified
  - Healthcare settings allowed to dispense limited
  - Patients utilizing the drug have safe use confirmation (lab tests, etc.)
  - Patient enrollment & specific monitoring
- Since March 25, 2008, 21 REMS Approved:
  - REMS for certain Opioids has been proposed and is currently being reviewed by the FDA

FDA's Action to Halt Marketing of Certain Unapproved Narcotic Drugs

- FDA sent warning letters March 30, 2009 to nine companies directing the companies to stop making and distributing 14 unapproved narcotic drugs marketed in several dosage forms
- Affected products included unapproved high concentrate oral solutions containing morphine sulfate and unapproved immediate release tablets containing morphine sulfate, hydromorphone, or oxycodone
- On April 9, 2009, FDA announced it was amending its previous action to allow continued marketing of a high concentrate morphine sulfate solution on an interim basis due to complaints form the pain mgmt. community.

FDA Action to Halt Marketing of Certain Unapproved Narcotic Drugs

- This is not a recall and previously manufactured products may still be found on pharmacy shelves for a short period of time
- FDA states that "Consumers will continue to have access to FDA-approved narcotic drugs"
- FDA is working to ensure that all marketed unapproved drugs obtain approval or are removed from the market